

REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claims 1-7 are pending herein. Claim 1 has been amended to recite:

A method of producing a product for improving immune-function in mammals,
comprising: Use of *Lactobacillus reuteri* strains
selecting a strain of *Lactobacillus reuteri* that

- c. exhibit exhibits good toxin binding and neutralizing effect; and
- d. exhibit exhibits good CD4+ cell recruitment, and
for the production of a composition for improving immune function in
mammals

formulating the product to contain cells of the strain of *Lactobacillus reuteri*.

Support for this terminology is found in original claim 1.

Claim 7 has been amended to recite: The product of claim 2 wherein the product is formulated as a an oral drug containing cells of the selected strain for improving
the immune-function of a patient.

Support for this terminology is found at page 9, lines 2-4, and page 12, lines 3-5.

In the Office Action of October 5, 2007, the Examiner took the following actions to which Applicant herein makes response: (1) rejected claim 8 under Section 112, first paragraph as not being described so as to enable making and/or use of the invention; (2) rejected claims 1-8 under Section 112, second paragraph as being indefinite, stating that claims 1 and 8 do not set forth any steps involved in the method/process, and further quoting two recitations that the Examiner states are in the claims and are indefinite, and rejection of claim 7; (3) rejected claims 1-8 under Section 101 stating that no steps are set forth in the process; (4) provisionally rejected claim 8 on the ground of nonstatutory obviousness-type double patenting over claim 9 of copending SN 11/147,880 (applicant's BIOA5108); and (5) rejected claims 1-8 under Section 102(a,e) as being anticipated by Farmer (6,461,607). These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 1-7 now pending in

the application.

(1) Rejection of claim 8 under Section 112, first paragraph as not being described so as to enable making and/or use of the invention

Claim 8 has been canceled and therefore this rejection is now moot.

(2) Rejection of claims 1-8 under Section 112, second paragraph as being indefinite, stating that claims 1 and 8 do not set forth any steps involved in the method/process, two recitations that the Examiner states are in the claims and are indefinite, and rejection of claim 7

Claim 1 has been amended to recite specific steps which are set forth in bold: A method of producing a product for improving immune-function in mammals, comprising: **selecting a strain of *Lactobacillus reuteri* that**

- a. exhibits good toxin binding and neutralizing effect; and
- b. exhibits good CD4+ cell recruitment, and

formulating the product to contain cells of the strain of *Lactobacillus reuteri*.

Applicant therefore respectfully submits that claim 1 as amended is definite and meets the requirements to set forth steps of Section 112, second paragraph. It is therefore submitted that claim 1 as amended, and claims 2-7, which depend from claim 1 as amended, now specifically set forth steps involved in the method, and are definite and patentable under Section 112, second paragraph.

The Examiner further rejected claims 1-7 “for the recitation of ‘i.e. by antibody test’ and ‘e.g. with immunohistochemical immunofluorescent methods’ because the use of these examples in the claims is not permitted”. The undersigned attorney is unclear where in the claims the Examiner is finding this terminology, because the specific location(s) for this terminology in the claims was not pointed out by the examiner. She has reviewed the international application as published, from which this application claims priority, as well as the files of the undersigned attorney, and does not find these terms in the claims. Because the undersigned attorney was not the attorney who originally filed the priority international application, it is of course possible that this terminology appears somewhere

in the file, but since the examiner did not refer to specific claims where these terms appear, and review by the undersigned attorney of all matters in her files does not produce these terms in a claim, Applicant is unable to address this rejection further, and in particular, cannot show amendment of an unknown claim.

The pending claims (as far as the undersigned attorney is aware and as amended herein) are set forth above on page 2, and do not include this terminology. The inventors of the instant invention, and any prior attorneys who may have worked on this application have been unavailable to the undersigned attorney and therefore she is unable to resolve this point without further elucidation by the Examiner of the specific grounds of rejection.

Applicant does respectfully request deletion by Examiner's amendment of any such unacceptable examples in the claims, if such are found in the claims, since Applicant is unable to do so.

The Examiner also stated that claim 7 was vague and indefinite because it was unclear what kind of drug is being claimed. Applicant has amended claim 7 to recite: "...wherein the product is formulated as an oral drug containing cells of the selected strain for improving the immune-function of a patient." Applicant respectfully submits that the terminology of claim 7 is now definite and that claim 7 is fully patentable under Section 112, second paragraph.

Claim 8 has been canceled.

Applicant submits that claims 1-7 now pending herein are therefore patentable under Section 112, second paragraph, for all the reasons set forth above.

(3) Rejection of claims 1-8 under Section 101 stating that no steps are set forth in the process

Applicant has amended claim 1 to recite specific steps as set forth above, and therefore it is submitted that claim 1 is patentable under Section 101. Claims 2-7 depend from and contain all of the limitations of claim 1 as amended and are therefore submitted to be similarly patentable under Section 101. Claim 8 has been canceled.

(4) Provisional rejection of claim 8 on the ground of nonstatutory obviousness-

**type double patenting over claim 9 of copending SN 11/147,880 (applicant's
BIOA5108)**

Claim 8 has been canceled and therefore this rejection is now moot.

**(5) Rejection of claims 1-8 under Section 102(a,e) as being anticipated by Farmer
(6,461,607)**

Applicant respectfully submits that Farmer's patent for "probiotic, lactic acid-producing bacteria and uses thereof" (title) "relates to the utilization of one or more species or strains of lactic acid-producing bacteria, preferably strains of *Bacillus coagulans*" (abstract) for treatment of gastrointestinal infection.

The examiner specifically refers to column 12, lines 44-50, which only discusses that a probiotic bacteria suitable in the invention of Farmer "possesses the ability to produce lactic acid", "demonstrates beneficial function within the gastrointestinal tract" and "is non-pathogenic". These characteristics are true of many different lactic acid bacteria probiotics, having a wide variety of functions and characteristics, including those specifically required by Farmer's claimed invention (a *Bacillus coagulans* that for example, "is resistant to a macrolide antibiotic... (Farmer's claim 2) or "is resistant to a cephalosporin antibiotic... (Farmer's claim 5).

Column 13, line 8, referred to by the Examiner, simply is part of a long list of well-known probiotic *Lactobacillus* bacteria.

Applicant respectfully submits that nothing in the cited passages of Farmer, nor elsewhere in Farmer teaches selecting a strain of *Lactobacillus reuteri* (or anything else) that exhibits good toxin binding and neutralizing effect; and exhibits good CD4+ cell recruitment according to claim 1 herein as amended. The fact that Farmer and many others before Farmer knew that many *Lactobacillus* species are good choices for probiotic use does not anticipate Applicant's specific selection criteria from within one of these species (*Lactobacillus reuteri*) nor selection of the strains selected by Applicant according to claim 1 as amended, nor products utilizing strains selected on this basis. In fact, Farmer does not teach or suggest that such strains might exist.

Applicant therefore respectfully submits that claim 1 as amended, and claims 2-7,

which depend therefrom, are patentable under Section 102(a,e) over Farmer. Claim 8 has been canceled.

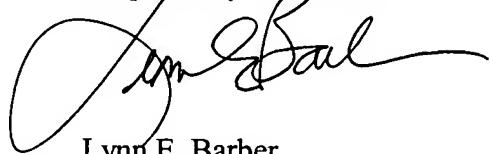
Conclusion

For all the foregoing reasons, claims 1-7 are submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

Applicant submits that no new claims have been added and therefore that no fee is required for the presentation of this amendment except for the separately submitted fee for extension of time. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



Lynn E. Barber
Attorney for Applicants
Registration No. 31,734
P.O. Box 16528
Fort Worth, TX 76162
(817) 361-7131